K003159

OCT 3 0 2000

510(k) Summary

Attachment 1

Summary of Safety and Effectiveness

Submitter:

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Contact person:

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Manager, Regulatory Affairs
Cordis Corporation, a Johnson & Johnson Company
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USA

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Date prepared

05 October 2000

General provisions

Trade name: Cordis **SLALOM** PTA Balloon Catheter.

Common Name: Peripheral Transluminal Angioplasty Balloon Catheter.

Classification Name: 21 CFR 870.1250: Percutaneous Catheter.

Device Classification

Class II.

Name of predicate devices

Cordis **PowerFlex plus** PTA Balloon Catheter
Cordis **PowerFlex Extreme** PTA Balloon Catheter

Performance standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Intended Use and device description	The **SLALOM** PTA catheter is intended to dilate stenosis in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. In addition, certain sizes of the **SLALOM** catheters are indicated for deployment of Cordis stents. This is the same intended use featured with the predicate devices. The Cordis **SLALOM** PTA Balloon Catheter is a dual lumen design with a distal inflatable balloon. Two radiopaque marker bands indicate the dilating section of the balloon and aid in balloon and stent placement.
Biocompatibility	All materials used in the **SLALOM** PTA Balloon Catheter are biocompatible.
Performance Data	The safety and effectiveness of the **SLALOM** PTA Balloon Catheter has been demonstrated via data collected from non-clinical design verification tests and analysis.
Summary of Substantial Equivalence	The **SLALOM** PTA Balloon Catheter is substantially equivalent to the previously cleared **PowerFlex Plus** and **PowerFlex Extreme** PTA Balloon Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2000

Cordis Corporation
c/o Mr. Chuck Ryan, RAC
Manager, Regulatory Affairs
7 Powderhorn Drive
Warren, NJ 07059

Re: K003159
Trade Name: Cordis SALOM™ 0.018" PTA Balloon Catheter
Regulatory Class: II (two)
Product Code: LIT, and DQY
Dated: October 6, 2000
Received: October 10, 2000

Dear Mr. Ryan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

Indications for Use Statement

510(k) Number (if known)	K***** K003159
Device Name	Cordis **SLALOM** PTA Balloon Catheter
Indications for Use	The **SLALOM** PTA catheter is intended to dilate stenosis in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. In addition, certain sizes of the **SLALOM** catheters are indicated for deployment of Cordis Stents as follows: ➢ **4 – 7 mm diameter x 4 cm** length **SLALOM** for use with the 39 mm Palmaz Corinthian IQ balloon-expandable Stent. The clinical indications for these stents are described in the applicable stent "Directions for Use".

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003159